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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,841	02/20/2004	Masato Horie	Q-76526	5773

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,841	HORIE, MASATO	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/820,170

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/17/06, 2/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Non-Final Rejection

Claims 30-33 are pending.

The cancellation of claims 29 and 34-35 and the amendment to the specification filed on 6/8/06 is acknowledged and considered by the examiner.

Election/Restrictions

Applicant's election without traverse of claims 30-33 in the reply filed on 6/8/06 is acknowledged.

The election/restriction is moot because of the cancellation of claims 29 and 34-35.

Information Disclosure Statement

The information disclosure statement filed 2/20/04 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the author is missing from the NPL documents. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

The examiner has considered the European Search Report.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 08/820,170, filed on 3/19/97.

Claim Rejections - 35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-33 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a substantial or well-established utility.

The instant specification contemplates that the novel human NRP1 gene is provided and the use of said gene makes it possible to detect the expression of said gene in various tissue and product the human NRP1 protein by the technology of genetic engineering. NRP1 can further be to study in brain neurotransmission system, diagnosis of various diseases related to neurotransmission in the brain, and the screening and evaluation of drugs for the treatment and prevention of such diseases (page 90-91). The NRP might be secretory proteins or proteins anchored to membranes as a result of posttranslationation modification (page 89). The applicant speculates that NRP might function as ligands by stimulating other molecules such as EGF

receptors (page 89). Furthermore, the EGF-domain containing NRP could act as growth factors in brain and may be useful in the diagnosis and treatment of various kinds of intracerebral tumor and effective in nerve regeneration in cases of degenerative nervous diseases (page 91). The domains of NRP suggest that NRPs might play a role as signal molecules for growth regulation (page 90). Applicant further suggests that these genes might have particular function in kidney (page 90).

The claims are drawn to an isolated nucleic acid molecule encoding a nel-related protein type 1 (NRP1, also known as NELL1) consisting of the DNA sequence in SEQ ID NO: 35. At the time the invention was made, it was unknown that SEQ ID NO: 35 or a nucleic acid sequence encoding SEQ ID NO: 34 were associated with a role in having cranial nerve growth activity and/or nerve regenerating activity. The instant specification does not teach what activity is related with expression of NRP1. The instant specification provides no nexus between the 'association' of the claimed nucleic acid molecule with cranial nerve growth and/or nerve regeneration.

With respect to using the claimed polynucleotides or products made directly or indirectly from the nucleic acid molecule in either an *in vitro* or an *in vivo* screening assay comprising observing an increase or a decrease of the claimed DNA products or NRP1-associated gene products, the instant specification does not teach what to look for as a result of an increase or a decrease in expression of SEQ ID NO: 34 encoded by a DNA sequence or a polynucleotide comprising SEQ ID NO: 35. One skilled in the art would have to further experiment on the invention to determine what results are observed with either an increase or a decrease in expression of SEQ ID NO: 34 in a genus of cells, including neurons (nerve cells). In absence of

the instant specification teaching what to look for in the assays, the claimed invention lacks utility.

In addition, with respect to using the claimed nucleic acid molecule or products made directly or indirectly from the sequences, the instant specification provides no evidence that SEQ ID NO: 35 or a nucleic acid encoding SEQ ID NO: 34 is involved in intracerabral tumor or degenerative nerve diseases. The specification provides no evidence that the claimed DNA sequences are associated with any specific disease (e.g., tumor, kidney disease, degenerative nervous disease). It would require further experimentation on the claimed invention/or products made directly or indirectly from the DNA sequences to determine whether they were involved in intracerabral tumor or other disease(s). Thus, the asserted utilities set forth above do not provide a benefit to the public in currently available form. See Ziegler, 992 F.2d at 1203, 26 USPQ2d 1600 (Fed. Cir. 1993).

At pages 88-89 of the specification, the applicant teaches the result of homology analysis for NRPs and nel. The applicant and prior art teach that NRP1 has 50% homology to chick embryonic nel (page 88). NRP1 is considered not to be a human counterpart of nel, but a homologous gene (page 89). The domains of NRP suggest that NRPs might play a role as signal molecules for growth regulation (page 90). The instant specification and the prior art are absent for an undefined NRP protein having several EGF-like repeats. The skilled artisan understands that EGF repeats are present in several proteins with different functions. At page 90, applicant teaches that Northern blot analysis, it was found that NRP1 was weakly expressed in fetal and adult brain and kidney. The office conducted a sequence search of the polynucleotide sequence set forth in SEQ ID NO: 35 against nucleotide public databases. The results from the

polynucleotide sequence databases search did not display any sequence similarity with any known gene associated with cranial nerve growth and/or nerve regenerating activity. Sequences, at the time the application was filed, with the closest sequence similarity with SED ID NO: 35, besides nel, is fibrillin I, 11.7% identity (calcium-binding protein). Furthermore, a post-filing reference teaches that the precise role of Nell-1 is unknown (see Ting et al. Journal of Bone and Mineral Research, 14:80-89, 1999).

Since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention. See also In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967) and In Brenner v. Manson, 383 US 519, 148 USPQ 689 (1966). Also see REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS: www.uspto.gov/web/menu/utility.pdf.

Claims 30-33 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a well asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 30 is rejected under 35 U.S.C. 102(a) as being anticipated by Watanabe et al. (Genomics 38:273-276, 1996). Watanabe teaches novel human cDNAs (NELL1, also known as NRP1). NELL1 cDNA is 2977 bp (page 274). The DNA sequence taught by Watanabe would hybridizes with the DNA sequence defined in (a) of instant claim 30 under washing conditions of 0.1 x SSC/O.05% SDS at 50°C. In addition, since the DNA has the same structure as SEQ ID NO: 35 it would also be capable of expressing a polypeptide having cranial nerve growth activity and/or nerve regenerating activity. See Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999) and In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 30 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 29 of copending Application No. 10/342,276. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims embrace an isolated DNA sequence consisting of SEQ ID NO: 35.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The petition under 37 CFR 1.48(c) to correct inventorship is granted because it complies with the requirements under 37 CFR 1.48 (c) and the two co-inventors have been added to the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, SPE – Art Unit 1635, can be reached at (571) 272-4517.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman

BRIAN WHITEMAN
PATENT EXAMINER